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TITLE: BREAST CANCER EPIDEMIOLOGY IN PUERTO RICO

PRINCIPAL INVESTIGATOR: DR. CRUZ M. NAZARIO

CONTRACTING ORGANIZATION:
University of Puerto Rico
San Juan PR 00936-5067

REPORT DATE: June 2010

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Nazario,Cruz María PhD

Email: cnazario@rcm.upr.edu

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This third year report provides evidence that the training of investigators phase has been develop successfully. The infrastructure for developing the pilot case-control study has been completed. The work, communication and coordination between mentor institution, minority institution and the project agency sponsoring has been effective and this has stimulated the second phase of the study has been develop successfully (Recruitment and data collection).

15. SUBJECT TERMS

Breast cancer; population-based study, epidemiology,

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Annual Report, 03 June 1, 2009 – June 30, 2010
Breast Cancer Epidemiology in Puerto Rico
BCRP HBCU/MI Partnership Training Award BC060131
CDMRP Grant W81XWH-07-1-0329

Cruz María Nazario, Ph.D.
Department of Biostatistics and Epidemiology, Office A-463
School of Public Health
University of Puerto Rico; Medical Sciences Campus
PO Box 365067, San Juan, Puerto Rico 00936-5067
(787) 758-2525 ext. 1429; cruz.nazario@upr.edu

Cruz María Nazario, Ph.D.; Principal Investigator
Jo Freudenheim, PhD; Principal Investigator, Mentor

Date of Publication: June 30, 2010

Grants Officer's Representative: Theresa J. Miller, Ph.D.

INTRODUCTION:

This project has two mayor goals: to design and conduct a pilot case-control breast cancer study among Puerto Rican women and to train and develop researchers in breast cancer at the minority institution. The case-control study will enroll women 30-79 years of age who are residents of the San Juan metropolitan area. Cases will be women with incident, primary, pathologically confirmed breast cancer with no history of previous cancer other than non-melanoma skin cancer; controls will be frequency-matched by age and randomly selected from female residents of the same geographical area as the cancer cases. We will examine adult and childhood factors in relation to risk of breast cancer in this understudied population of Puerto Rican women. The specific aims are: to examine dietary risk factors in relation to breast cancer and also in relation to tumor characteristics; to examine other established risk factors such as lifetime weight gain, physical activity, alcohol consumption, and reproductive history among Puerto Ricans in relation to breast cancer risk; and to examine factors related to early life exposure including birth weight, childhood diet, physical activity, environmental factors and residential history as a proxy for environmental exposure. The overall training goal is to develop a team of independent investigators with the necessary skills to develop a program of breast cancer research in Puerto Rico and to obtain funds and support for that research. To accomplish this goal, researchers from the University of Puerto Rico will obtain formal training in cancer epidemiology and participate in the design and conduct of the population-based case control study.

BODY:

STATEMENT OF WORK

Task 1. Training researchers from the University of Puerto Rico

The training of investigators at the minority institution has been an important goal in this project. Investigators have been involved in activities directed toward achieving the following goals: 1) to develop expertise in breast cancer epidemiology, especially in the areas of interest for the planned study, 2) to understand cutting edge developments in breast cancer in order to design future studies to test new hypothesis and 3) to develop needed expertise specially for the planned as well as for future studies.

In order to meet the training goals, during the third year of the award, the investigators have participated in the following scientific activities. Dr. Mansilla attended the Joint Annual Conference of the International Society for Environmental Epidemiology (ISEE), held in Dublin, Ireland, from August 25 – 29, 2009. In this conference Dr. Mansilla participated in a pre-conference workshop on "DAEviromental Health: Introduction to Causal Diagrams and Their Application in Environmental Epidemiology Research"

Dr. Michele Schelske-Santos attended the Experimental Biology (EB) Annual Meeting in April 2010. In this meeting Dr. Schelske-Santos participated in several sections related to dietary, physical activity patterns, lifestyles and breast cancer.

Johan Hernandez, MPH, the Program coordinator attended the American Public Health Association's 137th Annual Meeting & Exposition: Water and Public Health, in November 2009. She attended sessions on: Epidemiology Education –The many faces of epidemiology training in today dynamic and global public health, Health Disparities and Epidemiology, Cancer Epidemiology Section I, Genetic and Molecular Epidemiology and Breast Cancer Awareness, Screening and Control Innovative Strategies for Reducing Disparities.

Dr. Cruz Maria Nazario attended the 15th Puerto Rico Breast Cancer Conference, held in San Juan PR, October 2009. At the conference, Dr. Nazario attended sessions on breast cancer prevention, screening and histopathology. Dr. Nazario also attended the AACR special conference on Epigenetic of Cancer, January 2010 and the American Association of Cancer Research 101st Annual Meeting in April 2010. At both of these conferences, Dr. Nazario participated in several sessions related to cancer biology from basic through clinical and epidemiological research. She also met with other researchers at the meeting to discuss ideas for future studies on breast cancer risk. Also, Dr. Nazario met with Dr. Jo Freudenheim (Co- investigator and mentor) and Dr. Theresa J. Miller (Task Manager, Congressionally Directed Medical Research Programs) to discuss issues regarding the study protocol (interview process, biological sample and other).

In addition, researchers from the minority institution (University of Puerto Rico) participated in summer courses in Cancer Epidemiology (July 2009). Dr. Mansilla attended a course on "Molecular Epidemiology of Cancer", offered by the 44th Graduate Summer Session on Epidemiology, The University of Michigan, School of Public Health, Ann Arbor, Michigan. July 13-17, 2009. The objectives of this course were: (1) to introduce students to basic concepts in the molecular epidemiology of cancer, design considerations for gene-environment interaction, and statistical methods for analyzing haplotype data; (2) to discuss practical issues such as biologic specimen collection, processing and banking of samples, and quality control in the laboratory; (3) to understand methodological issues related to the major categories of biologic markers (exposure, susceptibility, and early biologic response); and (4) to review current research in the molecular epidemiology of cancer. The course explored concepts and issues found at the interface of the basic sciences and cancer epidemiology, including discovery of new biomarkers, whole genome association studies, expression profiling and proteomics, and development of new technologies for cancer screening. Students were asked to apply the knowledge gained to a particular problem in cancer epidemiology.

Dr. Rosario took a course on Social Epidemiology at Johns Hopkins Bloomberg School of Public Health Baltimore, MD. June 29 to July 3, 2009. This course offered an overview of conceptual and methodological approaches relevant to the study of the impact of social factors on the population health.

These activities were all important for our goals of understanding cutting edge science related to breast cancer and cancer biology more generally and to develop needed expertise especially for the planned studies as well as for future studies on breast cancer.

Task 2. Develop and maintain communications among participating investigators.

During the third year of the award, the minority and the mentoring institutions have been in close communication to discuss relevant issues regarding the study protocol. The primary means of communication has been by weekly teleconference calls of at least one hour, as well as frequent communications by email. In addition, the Puerto Rican investigators meet to discuss issues of study design and implementation before and after the conference calls. In addition, the investigators from both institutions met in person to discuss the progress of the project. Dr. Freudenheim traveled to Puerto Rico and met with investigators there. In addition, Dr Nazario met with Dr Freudenheim at the AACR meeting.

Task 3. To design, implement and analyze a case control study of breast cancer in Puerto Rico.

During these past months both institutions have been in close communication to conduct the study protocol. Approval of the study informed consent and protocol was obtained from all study institutions (University of Puerto Rico, University at Buffalo and Roswell Park Cancer Institute) and submitted to Human Subjects Protection Scientist of the CDMRP IRB in October 2009. All research instruments to be used in this study were

completed in November 2009 (questionnaire, manuals, data sheet of measures and samples and other).

All personnel training related to the study protocol were completed (Community Outreach training, Nurse training and Interviewer training). An electronic version of the questionnaire was developed using Microsoft Access. At this moment we are testing the electronic version of the questionnaire and we hope to complete the revision by July 2010. We plan re-training the interviewer in the use of this electronic version early in August 2010.

Task4. Study participants' recruitment and data collection to conduct a breast cancer case-control study in Puerto Rico.

The recruitment of human subjects and data collection for the study protocol started in November 2009. The geographical area from which cases and controls will be drawn has been defined as the following municipalities: San Juan, Bayamón and Guaynabo.

Cases ascertainment and recruitment

The Principal Investigator (Dr. Nazario) and the Project Coordinator (J. Hernandez) identified the physicians and institutions where most of the breast cancer patients from this geographic region are being treated using data from the Puerto Rican cancer registry. They established collaborations with those hospitals and physicians to allow us to ascertain all the incident breast cancer cases in the region. At this time, twenty four primary physicians (or referring physicians) and two hospitals (with oncology clinics) have agreed to identify sources of cases and coordinate the case recruitment. At the time of this report we have received 192 referrals of potential breast cancer cases. The first scrutiny identifies area of residence and age of potential participant. The project staff has contacted 96 breast cancer cases to further evaluate the eligibility criteria to participate in the study. Of these 96 contacted cases, 63 are eligible to participate in the study and 56 have agreed to participate. We are in the process of arranging for and completing interviews for this group.

Control ascertainment and recruitment

A list of randomly selected households in the study region is being used to identify potential population controls. This list was given to a Community Outreach worker who began control recruitment in November 2009. The Community Outreach worker has contacted 122 potential controls who are eligible to participate in the study. Of these 122 potential controls, 84 (69%) have agreed to participate in the study and the project staff has scheduled an appointment for the study.

For both cases and controls, we are monitoring ascertainment and recruitment procedures to optimize response rates. The data collection phase began in November 2009. At the end of this report, 140 interviews had been coordinated. The following table describes the interviewing up to June 30, 2010.

Interview	Control	Cases	Total
Completed	65	37	102
In process	19	19	38
Total of Coordinated Interviews	**84**	**56**	**140**
Interview completed percent (%)	**77%**	**66%**	**73%**

At this moment, no problems have been anticipated that could impede the progress of this project. Nevertheless, due to the extensive time lag to obtain human subject approval, participant recruitment started later than anticipated. We plan to finalize the electronic version of the questionnaire in August 2010; we will use the electronic version at that time. Our goal is to complete as many interviews as we can in the remaining period of the grant. .

KEY RESEARCH ACCOMPLISHMENTS:

- Training of study investigators in basic epidemiology and nutrition epidemiology (Appendix A).
- Finalization of questionnaires, IRB approval by the funding agency and all participating institutions, identification of sources for case ascertainment, implementation of interviewing of participants.

REPORTABLE OUTCOMES:

- Informed Consent fully approved in local (UPR-Medical Sciences Campus) and DOD-CDMRP IRB Committee (Appendix B).

CONCLUSION:

This third year report provides evidence that the training of investigators phase has been successfully implemented. The infrastructure for developing the pilot case-control study has been completed. The work, communication and coordination between mentor institution, minority institution and the project agency sponsoring has been effective and this has stimulated the second phase of the study has been completed successfully (Recruitment and data collection).

REFERENCES: N/A

APPENDIX:

- Progress and Training Report of study investigators in basic epidemiology and nutrition epidemiology (Appendix A)
- Informed Consent fully approved in local (UPR-Medical Sciences Campus) and DOD-CDMRP IRB Committee (Appendix B).

Breast Cancer Epidemiology in Puerto Rico
Annual Report (3)
June 2009 to June 2010

Appendix A
Progress and training report of study investigators

Dr. Cruz M. Nazario (Principal Investigator)

1. Weekly conference call with investigators from Puerto Rico and Dr. Jo Freudenheim from the University at Buffalo.

2. Weekly meeting with project coordinator.

3. Training

    a. Attendance to Conferences and Annual Meetings:

        i. The 15th Puerto Rico Breast Cancer Conference, held in San Juan PR, October 2009.
            1. I attended sessions on breast cancer prevention, screening and histopathology.

        ii. AACR Special Conference in Cancer Epigenetic, held in San Juan PR, January 2010
            1. I attended sessions on cancer epigenetic and participated in workshop was held to discuss the bioinformatics challenges of whole genome epigenetic analyses.
            2. I met with Dr. Jo Freudenheim (Co- investigator and mentor) to discuss relevant issues regarding the study protocol development (recruitment, interview process, biological sample and other)

        iii. The American Association of Cancer Research 101st Annual Meeting, held in Washington DC, April 2010.
            1. I participated in several sections related to cancer science from basic through clinical and epidemiological research.
            2. I met with researchers participating in the meeting to discuss ideas for future studies on breast cancer risk.
            3. I met with Dr. Jo Freudenheim (Co- investigator and mentor) and Dr. Theresa J. Miller (Task Manager, Congressionally Directed Medical Research Programs) to discuss relevant issues regarding the study protocol (interview process, biological sample and other)

Dr. Michelle Schelske-Santos **(Co-investigator)**

1. Weekly conference call with Dr. Jo Freudenheim (University at Buffalo) and Puerto Rico investigators team.

2. Training
    a. Attendance to Annual Meetings:
        i. The Experimental Biology (EB) Annual Meeting in April 2010.
            1. I participated in several section directly related to dietary, physical activity patterns, lifestyles and Breast Cancer.

Dr. Imar Mansilla-Rivera **(Co-investigator)**

1. Weekly conference call.

2. Training
    a. Courses:
        i. Attended a course on "Molecular Epidemiology of Cancer", offered by the 44th Graduate Summer Session on Epidemiology, The University of Michigan, School of Public Health, Ann Arbor, Michigan. July 13-17, 2009. The course explored concepts and issues found at the interface of the basic sciences and cancer epidemiology, including discovery of new biomarkers, whole genome association studies, expression profiling and proteomics, and development of new technologies for cancer screening. Students were asked to apply the knowledge gained to a particular problem in cancer epidemiology.

    b. Attendance to Annual Meetings:
        i. The Joint Annual Conference of the International Society for Environmental Epidemiology (ISEE), held in Dublin, Ireland, from August 25 – 29, 2009.
            1. I participated in a pre-conference workshop on "DAGviromental Health: Introduction to Causal Diagrams and Their Application in Environmental Epidemiology Research

Dr. Rosa Rosario (Co-investigator)

1. Weekly conference call.

2. Training:

    a. Courses:
        i. Attended a course on Social Epidemiology at Johns Hopkins Bloomberg School of Public Health Baltimore, MD. June 29 to July 3, 2009. This course offered an overview of conceptual and methodological approaches relevant to the study of the impact of social factors on the population health.

Johan Hernandez, MPH (Project Coordinator)

1. Weekly meeting with principal investigator and other staff project.

2. Training:
    a. Attendance to Annual Meetings:
        i. The American Public Health Association's 137th Annual Meeting & Exposition: Water and Public Health, in November 2009.
            1. *I* attended several conferences and workshop on cancer epidemiology:
                a. Epidemiology Education –The many faces of epidemiology training in today dynamic and global public health.
                b. Health Disparities and Epidemiology
                c. Cancer Epidemiology Section I
                d. Genetic and Molecular Epidemiology and Breast Cancer Awareness
                e. Screening and Control Innovative Strategies for Reducing Disparities.

UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MÉDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

OFICINA DEL RECTOR
OFFICE THE CHANCELLOR

COMITÉ DE DERECHOS HUMANOS (IRB)
INSTITUTIONAL REVIEW BOARD

Date: February 02, 2010

Protocol Number: 0750108

Principal Investigator: Dr. Cruz M. Nazario

Department / Division: School of Public Health - Epidemiology

Sponsor:

Title: ***Breast Cancer Epidemiology in Puerto Rico***

This is to certify that the above referenced research proposal/protocol was evaluated on **February 02,2010** and meets **expedite** IRB review category. The research proposal was **approved.** A progress report (continuing review) is due in one year and/ or at the end of the study.

This action involves:

☒ Continuing Review **#2** of Previously Approved Protocol

☐ Data Analysis

The following documents were reviewed under this submission:

☒ Informed Consent Document
English and Spanish Version 1/9/10 -
Main and Donors Consents

☒ Others: Annual Report 2008-09

In compliance with federal regulations, the approval for this study is valid through: **February 01, 2011**
For additional information please contact Human Research Subjects Protection Office at 787-282-0010 or 787-282-0018; e-mail opphi.rcm@upr.edu.

Cordially,

María Del Rosario González
Chairperson IRB 1

rnco

1. Research must be conducted according to the proposal that was approved by the IRB.
2. Changes to the protocol or its related consent document must be approved by the IRB prior to implementation.
3. All serious or unexpected adverse events/drug reactions should be reported.
4. Each subject should receive a copy of the consent document, if appropriate.
5. Records must be retained for at least three years.
6. Any future correspondence should include the IRB identification number provided and the study title.

Universidad de Puerto Rico
Recinto de Ciencias Médicas
Escuela Graduada de Salud Pública
Apartado postal 365067, San Juan, Puerto Rico 00936-5067

CONSENTIMIENTO PARA PARTICIPAR EN ESTUDIOS DE INVESTIGACIÓN

TÍTULO: **Epidemiología de cáncer de mama en Puerto Rico**

NÚMERO DE PROTOCOLO:

PATROCINADOR:
Programa de investigación médica dirigido por el Congreso de los Estados Unidos para cáncer de mama, Departamento de Defensa CDMRP #BC060131USAMRMC-DOD

INVESTIGADORES: Cruz María Nazario-Delgado, Ph.D. (PI) Universidad de Puerto Rico
Jo Freudenheim, Ph.D. (Co-PI), University at Buffalo, Roswell Park Cancer Institute

Esta hoja de consentimiento puede contener palabras que usted no entienda. Por favor, pídale al investigador o a cualquier miembro del personal del estudio que le explique cualquier palabra o información que usted no entienda claramente. Usted puede llevarse a su casa una copia sin firmar de este consentimiento para pensar sobre este estudio o para discutirlo con su familia o amigos antes de tomar su decisión.

I - INTRODUCCIÓN

Usted ha sido invitada a participar en un estudio de investigación conducido por la Universidad de Puerto Rico, Recinto de Ciencias Médicas. Este proyecto recibe fondos del Programa de Investigación de Cáncer de Mama, bajo el mecanismo de Donativo para Adiestramiento en Colaboración con Universidades, Colegios e Instituciones de Grupos Minoritarios del Departamento de la Defensa. Sin embargo, antes de que usted decida participar en el estudio, por favor, lea este consentimiento cuidadosamente y haga todas las preguntas necesarias para asegurarse de que entienda los procedimientos del estudio, los riesgos y los beneficios.

II – PROPÓSITO DEL ESTUDIO

Estamos conduciendo un estudio para entender cómo la dieta, la actividad física, el historial familiar y las exposiciones tempranas, además de otros factores, están relacionados con el riesgo de cáncer del seno. Otros investigadores han estudiado estos factores en otras poblaciones. Nosotros queremos examinar la relación de esos factores de riesgo de cáncer del seno en mujeres que viven en Puerto Rico. Estos factores incluyen el consumo de alimentos que son ricos en vitaminas y antioxidantes. Los investigadores creen que estos alimentos pueden protegernos.

Hay indicios de que algunas exposiciones a través de nuestra vida son factores de riesgo importantes para el cáncer del seno. Por eso, necesitamos entender mejor las exposiciones que a través de la vida de la mujer pueden protegernos o aumentar el riesgo de cáncer del seno. Al igual que la gente se ve diferente, también hay diferencias en la forma que nuestro cuerpo maneja la exposición a lo que comemos, tomamos, fumamos y a los medicamentos que usamos. Un estudio en nuestra población puede proveernos mejor información sobre los factores que protegen o aumentan el riesgo de cáncer del seno en las mujeres en Puerto Rico.

III – PARTICIPANTES DEL ESTUDIO

En este estudio podrán participar 500 mujeres con cáncer de seno que hayan tenido un diagnóstico reciente (hace un año o menos) confirmado por pruebas y por el médico, que tengan entre 30 y 79 años y residan en alguno de los siguientes municipios: San Juan, Bayamón y Guaynabo. También podrán participar 500 mujeres que no tengan cáncer, a menos que haya sido cáncer de piel (no-melanoma) y que tengan entre 30 y 79 años y residan en alguno de los municipios mencionados anteriormente. Las mujeres menores de 30 o mayores de 79 años o que vivan en otros municipios fuera del área de estudio no podrán participar. La participación en este estudio es voluntaria y usted puede negarse a participar. Puede decidir no continuar en el estudio en cualquier momento, sin que implique alguna penalidad y no perderá los beneficios que le corresponden.

IV - PROCEDIMIENTOS

Si acepta a participar en este estudio, necesitamos que consienta y nos permita recoger información por medio de un cuestionario y tomar y analizar una muestra de tres tubitos de sangre (tubitos de 0.5 ml) en ayunas (siempre que sea posible). Si no puede donar una muestra de sangre, podemos tomarle una muestra de saliva para el análisis.

El procedimiento de tomar la muestra de sangre o de saliva es simple y el riesgo a su salud es mínimo. Una enfermera adiestrada del Centro de Investigaciones Clínicas del Recinto de Ciencias Médicas tomará estas muestras. La enfermera también le tomará las medidas siguientes: peso, estatura, medida de la cintura y caderas, medidas de pliegues de piel (tríceps, subescapular, supra- ilíaco, vientre y muslo) y medidas del color de piel en la mano y el brazo.

Después de estos procedimientos, le daremos una merienda y la entrevistadora le hará las preguntas del cuestionario. La entrevista dura aproximadamente 30 minutos y las preguntas están relacionadas a la dieta, la actividad física, el historial de peso, los hábitos de fumar, la exposición al sol, su información demográfica, su historial personal y familiar de enfermedades crónicas, su historial residencial, el uso de vitaminas y medicinas, información sobre la menstruación y los hijos que ha tenido, al igual que algunas preguntas sobre diagnóstico y tratamiento de cáncer. Una vez que terminemos la entrevista, usted habrá completado su participación en el estudio. El procedimiento completo no debe tardar más de una (1) hora.

Para este estudio usaremos muestras de sangre o saliva para estudiar cómo el cuerpo de una

mujer procesa y elimina de forma diferente los nutrientes, las hormonas y otras sustancias que pueden afectar el riesgo de cáncer. Estas diferencias pueden ser el resultado de los genes, que son las características que heredamos de nuestros padres. Es poco probable que las diferentes formas de esos genes causen enfermedades por si mismas. Es más probable que estos genes afecten la manera en que el cuerpo maneja las exposiciones y otros factores de riesgo. Debido a que la ciencia médica no conoce si estas diferencias afectan y tampoco conocen de qué forma afectan el riesgo de cáncer, usted no recibirá los resultados de estas pruebas ni los hallazgos que pudieran resultar. Los datos de este estudio serán analizados y presentados en forma de comparación de los grupos de mujeres con cáncer y las mujeres sin cáncer para estudiar el riesgo asociado a la exposición a diferentes genes. Además, estudiaremos otros compuestos en la sangre (nutrientes, hormonas, entre otros) para entender mejor estos procesos en las mujeres que viven en Puerto Rico. Su sangre será analizada en el laboratorio del Roswell Park Cancer Institute por científicos que colaboran con este estudio. La sangre y la saliva, no tendrá información personal que pudiera identificarla, y sólo estará identificada con un código numérico.

V – RIESGOS O INCOMODIDADES

Usted debe entender que este estudio no es para probar nuevos medicamentos o tratamientos. Los procedimientos para tomar una muestra de sangre o una muestra de saliva son sencillos y el riesgo es mínimo. Estos son procedimientos rutinarios en la clínica del Centro de Investigaciones Clínicas del Recinto de Ciencias Médicas de la Universidad de Puerto Rico. Usted debe entender que la muestra de sangre debe ser en ayunas (siempre que sea posible) y que la tomará una enfermera adiestrada para estos procedimientos. La extracción de sangre de las venas puede causar dolor, moretones, mareos y en raras ocasiones, infección. Las medidas de los pliegues de la piel pueden causar dolor, moretones o alguna incomodidad. Si siente alguna molestia o incomodidad habrá un área de descanso disponible y se le dará una merienda luego de que se le tome la muestra.

Usted debe entender que las preguntas del cuestionario no son sensitivas u ofensivas, pero algunas preguntas podrían considerarse moderadamente sensitivas (por ejemplo: el historial reproductivo). Una mujer profesional y adiestrada en estudios en salud pública le hará la entrevista. Hemos puesto mucho énfasis en adiestrar y supervisar a la entrevistadora para que la incomodidad de la entrevista sea mínima. Usted puede rehusar a contestar cualquier pregunta que le resulte incomoda. No habrá consecuencias negativas si usted se niega a contestar alguna de esas preguntas.

VI – BENEFICIOS

Es probable que usted no reciba ningún beneficio personal de este estudio. Este estudio no fue diseñado para tratar sus problemas de salud. Sin embargo, su participación en este estudio es muy importante porque nos ayudará a conocer los factores que afectan el riesgo de desarrollar cáncer en las mujeres que viven en Puerto Rico. Los resultados del estudio pueden aumentar nuestro conocimiento de cómo la dieta, la actividad física y el metabolismo hormonal están relacionados con el cáncer del seno en las mujeres en Puerto Rico. El número de mujeres en Puerto Rico que desarrollan cáncer del seno continúa en aumento.

VII – COSTOS

No hay ningún costo por las visitas del estudio.

VIII – INCENTIVO PARA EL PARTICIPANTE

Usted recibirá $25 por su participación en el estudio una vez que haya terminado de contestar el cuestionario para cubrir los gastos de transportación.

Durante este estudio, se le pedirá que done una muestra de sangre o saliva. Si usted lo autoriza, esa muestra puede ser usada en el futuro para otros estudios sobre los genes que regulan las hormonas y los procesos que afectan el riesgo de enfermar. Existe una posibilidad de que la sangre que usted done se use en otros estudios que puedan tener algún valor comercial. Si esta muestra que usted ha donado llegara a ser usada junto con la de otras personas para el desarrollo de un producto comercial, la Dra. Cruz M. Nazario y la Dra. Jo Freudenheim serán las dueñas y podrán patentizar el producto. Las doctoras Nazario y Freudenheim no la compensaran en este estudio ni en los estudios futuros por el uso de su muestra de sangre. No recibirá notificación sobre el uso futuro de la muestra.

IX - ALTERNATIVAS DE PARTICIPACIÓN

Este estudio no conlleva tratamiento médico. Usted puede rehusar a contestar cualquier pregunta del cuestionario si lo desea. Esto no tiene ningún efecto en los tratamientos que está recibiendo. Su participación es voluntaria.

X – PRIVACIDAD Y CONFIDENCIALIDAD (HIPAA)

Si elige participar, el investigador obtendrá información personal sobre usted y su salud en este estudio. Esto puede incluir información que puede identificarle. El investigador también puede conseguir, mediante el cuestionario, información sobre su salud que incluye: dieta, actividad física, historial de peso, uso de cigarrillos, exposición al sol, información demográfica, número de seguro social, historial personal y familiar de enfermedades crónicas, dirección actual e historial residencial, uso de vitaminas y medicinas, información sobre la menstruación y los embarazos y alguna información sobre el diagnóstico y tratamiento del cáncer. Si usted ha tenido un diagnóstico de cáncer de seno, obtendremos la información de la patología del Registro Central de Cáncer de Puerto Rico.

La información sobre usted y su salud que podría identificarla puede ser brindada a otros que colaboran en este estudio de investigación. El patrocinador analizará y evaluará los resultados del estudio. El personal del patrocinador y de sus consultores podrán visitarnos para observar cómo se hace el estudio.

Sin embargo, los datos con su información personal estarán guardados y custodiados en un archivo con llave y solamente el personal del estudio autorizado (las investigadoras principales, la coordinadora del estudio, la tecnóloga médica y la enfermera del estudio) tendrá acceso a ellos, según la reglamentación de HIPAA.

La información obtenida en este estudio será guardada sin la información personal en archivos electrónicos que sólo pueden ser usados con una clave. La información podrá ser revisada por el Comité de Derechos Humanos (IRB, por sus siglas en inglés) del Recinto de Ciencias Médicas de la Universidad de Puerto Rico, el Comité de Revisión Institucional del Hospital Español Auxilio Mutuo, el Comité de Derechos Humanos del Hospital Oncológico Isaac González Martínez y por la Oficina de Protección de los Derechos Humanos del Departamento de la Defensa (HRPO-USAMRMC, por sus siglas en inglés). Estas personas revisan, de forma independiente, la investigación según ha sido reglamentado. Su información será mantenida tan confidencial como sea posible bajo la ley. Está información no podrá ser protegida por las reglas de privacidad una vez que se divulgue a nuestros asociados y puede ser compartida con otros. Sin embargo, nuestros asociados en esta investigación también están acogidos a las leyes de protección de información personal de los participantes en la investigación.

Los resultados de esta investigación pueden ser publicados en revistas científicas o ser presentados en reuniones médicas pero su identidad no será divulgada.

Esta autorización estará vigente hasta el final del estudio, a menos que usted la cancele antes. Usted puede cancelar esta autorización en cualquier momento mediante un aviso escrito que debe enviar a la Investigadora Principal en la dirección siguiente:

Dra. Cruz María Nazario
Departamento de Bioestadística y Epidemiología
Escuela Graduada de Salud Pública
Recinto de Ciencias Médicas, UPR
PO Box 365067 San Juan, PR, 00936-5067

Si usted cancela esta autorización, el Investigador Principal no usará ni divulgará su información personal ni de su salud bajo la autorización de este estudio. Esta información sólo se divulgará en

caso de que se necesite la información personal de su salud para preservar la integridad científica del estudio. La información sometida antes de que usted cancele esta autorización puede ser utilizada por los asociados.

La autorización para el uso y el acceso de la información protegida de la salud para los propósitos de la investigación es totalmente voluntaria. Sin embargo, de no firmar este documento no podrá participar en este estudio.

XI – COMPENSACIÓN EN CASO DE DAÑO

En el caso de lesión física o mental como resultado de este estudio de investigación usted recibirá tratamiento médico sin costo alguno en el Hospital Universitario de la Universidad o en cualquier otro hospital designado por el Rector del Recinto de Ciencias Médicas de la Universidad de Puerto Rico. La Universidad de Puerto Rico no ofrecerá ninguna forma de renumeración directamente a usted. Sin embargo, al firmar está hoja de consentimiento, usted no renuncia a ningún derecho legal.

XII – PARTICIPACIÓN Y RETIRO VOLUNTARIOS

Su participación en este estudio es voluntaria. Usted puede decidir no participar o retirarse del estudio en cualquier momento. Su decisión no resultará en ninguna penalidad o pérdida de beneficios para los cuales tenga derecho. De ser necesario, su participación en este estudio puede ser detenida en cualquier momento por el investigador del estudio o por el patrocinador sin su conocimiento. Usted puede estar de acuerdo en donar una muestra de sangre o una muestra de saliva y de completar el cuestionario además de que se le tomen las medidas del cuerpo. Si decide participar, también puede en cualquier momento retirar su consentimiento y descontinuar su participación sin ningún perjuicio para usted y no se usarán los datos y las muestras serán descartadas de acuerdo al protocolo del laboratorio.

XIII – FONDOS PARA PAGAR EL ESTUDIO

Este estudio es subvencionado por un donativo del "*Congressionally Directed Medical Research Program's Breast Cancer Research Program*" (BCRP), del Departamento de la Defensa bajo el mecanismo de acuerdo para el adiestramiento en los Colegios y Universidades con estudiantes de grupos minoritarios en asociación con universidades en los Estados Unidos.

XIV – PREGUNTAS

Si tiene alguna pregunta sobre este estudio o sobre su participación en el mismo, o si piensa que ha sufrido alguna lesión asociada al estudio, usted puede contactar a la Dra. Cruz M Nazario en

el siguiente número de teléfono 787-758-2525 extensión 1-1429 o a Johan Hernández (Coordinadora del Proyecto) en el número 787-758-2525, extensión 1-1936.

Si tiene alguna pregunta sobre sus derechos como participante del estudio, puede contactar a la:
Oficina de Protección de Participantes Humanos en Investigación
Teléfono (787) 282-0018 o (787) 282-0010
Correo electrónico (E-mail): opphi.rcm@upr.edu

Si usted es paciente del Hospital Auxilio Mutuo, también se puede comunicar con el Dr. Armando Nazario, presidente del Comité de Revisión Institucional (IRB) al teléfono: (787) 250-7676.

O si usted es paciente del Hospital Oncológico Isaac González Martínez se puede comunicar con la Dra. Cristina Nery, Presidenta del Comité de Derechos Humanos del Hospital o con la Dra. Hilda Rivera, Coordinadora de Investigación al teléfono (787) 753-8433.

No firme este consentimiento a menos que haya tenido la oportunidad de hacer preguntas y recibir contestaciones satisfactorias para todas sus preguntas. Si firma y acepta participar en este estudio, recibirá una copia firmada, con el sello de aprobación de IRB y con la fecha de esta hoja de consentimiento para usted.

XV - CONSENTIMIENTO

He leído la información de esta hoja de consentimiento o se me ha leído de manera adecuada. He tenido la oportunidad de formular preguntas y todas mis preguntas sobre el estudio y mi participación han sido atendidas.

Yo autorizo el uso y la divulgación de mi información de salud a las entidades antes mencionadas en este consentimiento para los propósitos descritos anteriormente.

Al firmar esta hoja de consentimiento, no he renunciado a ninguno de mis derechos legales.

_____
Nombre del Participante

_____ _____
Firma del Participante (o marca) Fecha

_____
Nombre del Testigo (Si aplica)

_____ _____
Firma del Testigo (Si aplica) Fecha

_____ _____
Dra. Cruz María Nazario, Fecha
Firma de la Investigadora Principal

Las muestras pueden ser guardadas para estudios futuros
□ Sí (Iniciales del Participante _____) □ No, las muestras sólo pueden usarse en este estudio

University of Puerto Rico
Medical Sciences Campus
Graduate School of Public Health
P.O. Box 365067, San Juan, Puerto Rico 00936-5067

CONSENT TO PARTICIPATE IN RESEARCH STUDIES

TITLE: **Breast Cancer Epidemiology in Puerto Rico**

PROTOCOL NUMBER:

SPONSOR: **Congressionally Directed Medical Research Program's Breast Cancer Research Program, Department of Defense, CDMRP #BC060131 USAMRMC-DOD.**

INVESTIGATORS: Cruz María Nazario-Delgado, Ph.D. (PI) University of Puerto Rico
Jo Freudenheim, Ph.D. (Co-PI), University at Buffalo, Roswell Park Cancer Institute

This consent form may contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about it or to discuss it with family or friends before making your decision.

I - INTRODUCTION

You have been invited to participate in a research study conducted at the University of Puerto Rico-Medical Sciences Campus. This project is funded by a grant from the Congressionally Directed Medical Research Program's Breast Cancer Research Program (BCRP) under the Historically Black Colleges and Universities/Minority Institutions Partnership Training Award mechanism, Department of Defense. However, before you agree to take part in this study, please read this consent form carefully and ask as many questions as you need in order to be sure you understand the study procedures, including risks and benefits.

II - PURPOSE OF THE STUDY

We are conducting a project to examine how our diet, physical activity, family history, early life exposures, and other factors are related to breast cancer. Other researchers have studied these factors in other populations. We want to examine the relation of these factors to breast cancer risk among women living in Puerto Rico. These factors include the consumption of foods that are rich in vitamins and antioxidants. Investigators think that these could protect us.

There are indications that exposures throughout our life are important risk factors for breast cancer. That is why we need to better understand the exposures that could protect or increase the risk for breast cancer. Just as people differ from one another in how they look, they also differ in what goes on inside their bodies and in how their bodies handle exposures to the things we eat, drink, or smoke, and to the medications that we take. A study in our population will provide a better insight into the factors that protect or increase the risk of breast cancer in Puerto Rico.

III - STUDY PARTICIPANTS

In this study, 500 women aged 30-79, with newly diagnosed (within a year) and confirmed breast cancer, who are residents of San Juan, Bayamón and Guaynabo will be eligible to participate. Also, 500 women aged 30-79, without breast cancer, other than skin cancer, who are residents in one of the municipalities mentioned above, will also be eligible to participate. Women less than 30 years or over 79 years of age, as well as those women that live in other geographical areas of Puerto Rico are not eligible to participate. Your participation is voluntary and you may refuse to participate. You may also decline to continue participating at any moment during the study. Your decision will not result in any penalty or loss of benefits to which you are entitled.

IV - PROCEDURES

If you agree to participate in the study, we need your consent for us to collect information through a questionnaire and to collect and process a fasting (whenever possible) blood sample, about 3 tubes (0.5 ml tubes). If you can not give a blood sample, we ask you to provide a saliva sample for the analysis.

The procedure to collect the blood or the saliva sample is simple and the risk to your health is minimal. A trained research nurse from the Clinical Research Center, University of Puerto Rico, Medical Sciences Campus (CRC-UPR-MSC) will do this procedure. A nurse will measure your weight, height, waist, hips, skin folds (triceps, sub-scapular, supra-iliac, abdomen, and thigh), and underarm and hand skin color.

After these procedures, we will provide a snack, and the study interviewer will ask you some questions. The interview will take approximately 30 minutes and the questions are related to your diet, physical activity, weight history, smoking, sun exposure, demographic characteristics, personal and familial history of chronic diseases, residential history, vitamin and medication use, menstrual and reproductive information, as well as some questions about cancer diagnosis and treatment. Once the interview is over, you will have completed your participation in this study. The complete process should be over in less than 1 hour.

For this study, we will use samples of blood or saliva to study how a woman's body differently processes and eliminates nutrients, hormones, or other substances that may affect the

risk of breast cancer. These differences may be due to the genes, which are the characteristics that we inherit from our parents. It is unlikely that the presence of these different forms of a gene would cause diseases alone. It is more likely that they will affect the way that the body reacts to exposures or risk factors. Because medical science does not know whether or not or how these gene variants affect the health and risk for cancer, you will not receive the results of these tests nor any incidental finding from such tests. The data from this study will be analyzed and presented in groups, comparing women with cancer and women without, to study the risk associated with different forms of genes. We will also examine other compounds in the blood (nutrients, hormones, etc) to better understand the process of these substances in women that live in Puerto Rico. Your biological samples will be analyzed in Roswell Park Cancer Institute Laboratory by scientists collaborating in this study. The blood or saliva samples will not have your name or any other information that could identify you, as they will be identified by a numeric code.

V - RISKS AND DISCOMFORTS

You understand that this study will not test any new drug or clinical treatment. The procedures to collect the blood or saliva samples are simple and the risk to your health is minimal. These are standard medical procedures in the Clinical Research Center of the Medical Sciences Campus. You understand that the blood will be drawn while you are fasting (whenever possible) and it will be done by a trained nurse. Drawing blood from your arm may cause pain, bruising, lightheadedness and, on rare occasions, infection. Skin fold measurements could cause pain, bruising, and some discomfort. If you feel any discomfort, a rest area will be available, and after the blood draw, a snack will be provided.

You also understand that most questions in the questionnaire are not sensitive, but there are a few questions that could be considered as moderately sensitive (i.e., reproductive history). A professional woman, with training in conducting public health studies, will conduct the interview. Particular emphasis has been placed in the training and supervision of the interviewer in order to minimize the potential risks during the administration of the questionnaire. You can refuse to answer any question that makes you uncomfortable. There will be no negative consequence should you refuse to answer those questions.

VI - BENEFITS TO SUBJECTS

You may not receive any personal benefits from being in this study. This study is not being done to treat your health problems. Nevertheless, your participation in this study is very important because it will help us understand the factors that affect the risk of developing breast cancer among women living in Puerto Rico. The results of this study may improve our knowledge about how diet, physical activity, and hormone metabolism are related to breast cancer in Puerto Rico. The number of women getting breast cancer in Puerto Rico continues to increase.

VII – COSTS There are no charges for the study visits.

VIII - COMPENSATION FOR PARTICIPATION

You will be paid $25 for your participation in the study after the questionnaire is completed to compensate for traveling expenses.

During this study, you will be asked to provide a blood or a saliva sample. If you consent, this sample may be used for future analysis of genes that may influence disease risk. There is a chance that the samples that you are donating under this study may be used in other research studies and may have some commercial value. Should your donated sample lead to the development of a commercial product, Dr. Cruz M. Nazario and Dr. Jo Freudenheim will own it and may take action to patent and license the product. In such case, Drs. Nazario and Freudenheim will not compensate you for your participation in this study or for any future use of the sample you have given. You will not receive any notice of future uses of your samples.

IX – PARTICIPATION ALTERNATIVES

This study does not involve medical treatment. You may refuse to answer any question in the questionnaire. Your refusal will not impact the treatment you may be receiving. Your participation is voluntary.

X - PRIVACY AND CONFIDENTIALITY (HIPAA)

If you choose to participate in this study, the investigator will get personal information about you. This may include information that might identify you. The investigator may also get information about your health using a questionnaire including questions related to your diet, physical activity, weight history, smoking, sun exposure, demographic characteristics, social security number, personal and familial history of chronic diseases, actual address and residential history, vitamin and medication use, menstrual and reproductive information, as well as some questions about cancer diagnosis and treatment. If you had a breast cancer diagnosis, the pathological information will be obtained from the Puerto Rico Central Cancer Registry.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done. Data with your identifying information will be kept in a locked file cabinet and only authorized study personnel (Principal Investigators, Project Coordinator, Lab technician, and the clinical nurse) will have access to it according to the Health Insurance Portability and Accountability Act (HIPAA) according to the Health Insurance Portability and Accountability Act (HIPAA). The information obtained in this study will be collected and stored without personal identifiers and will be stored in password protected electronic data file. The records will be safeguarded following HIPAA regulations.

The information may be reviewed by the UPR Medical Sciences Campus Institutional Review Board (UPR MSC IRB), Hospital Auxilio Mutuo Institutional Review Board, Isaac González Martinez Oncology Hospital Human Rights Committee and the Human Research Protection Office of the Department of Defense (HRPO USAMRMC -DOD). They are a group of people who perform independent review of research as required by regulations. Your personal health information will be kept as confidential as possible under the law. However, your personal health information is no longer protected by the privacy rule once it is disclosed to our associates, and may be shared with others. Nonetheless, our research associate must also comply with the laws that protect the personal information of study participants.

The results of this research may be published in scientific journals or presented at medical meetings, but no information will be included that will reveal your identity.

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel this authorization at any time by sending a written notice to the principal investigator at the following address:

Dr. Cruz María Nazario
Biostatistics and Epidemiology Department
Graduate School of Public Health
Medical Sciences Campus, UPR
PO Box 365067 San Juan, PR, 00936-5067

If you cancel this authorization, the principal investigator will no longer use or disclose your personal health information under the authorization for this study, unless he/she needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. Information submitted before you cancel this authorization can still be used by the associates.

The Authorization for Use and Disclosure of Protected Health Information for research purposes is completely voluntary. However, if you do not sign this document you will not be able to participate in this study.

XI – COMPENSATION FOR INJURY

In the event of physical and/or mental injury resulting from this research study, you will receive medical treatment free of change at the University Hospital or any other hospital designated by the Chancellor or the Medical Sciences Campus of the University of Puerto Rico.

The University of Puerto Rico has no plans to provide any form of compensation directly to you. However, by signing this consent form you do not give up any legal rights.

XII – VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. You can agree to donate blood or a saliva sample and to complete a questionnaire that collects personal information, as well as your body measures are taken. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice, any collected data will not be included in the study, and blood will be discarded according to the laboratory procedure. The investigator may withdraw you from participating in this study if it is necessary. The decision may be made either to protect your health and safety by the investigator without your consent.

XIII – SOURCE OF FUNDING

This project is funded by the Congressionally Directed Medical Research Program's Breast Cancer Research Program (BCRP) under the Historically Black Colleges and Universities/Minority Institutions Partnership Training Award mechanism of the Department of Defense.

XIV – QUESTIONS

If you have questions regarding this study or your participation in this study or if at any time you feel you have experienced a research related injury, you may contact Dr. Cruz M. Nazario at this number: 787-758-2525 extension 1-1429 or Johan Hernández (Project Coordinator) at the

787-758-2525, extension 1-1936. If you have any questions about your rights as a research subject you may contact the

Human Research Subjects Protection Office
University of Puerto Rico
Medical Sciences Campus
Telephone 787-282-0018 or 787-282-0010
E-mail: opphi.rcm@upr.edu

If you are patient of the Hospital Auxilio Mutuo, also, you can communicate with Dr. Armando Nazario, President of the Institutional Review Board (IRB) at the phone 787 250-7676.

Or if you are patient of the Isaac González Martinez Oncology Hospital, you can communicate with Dr. Cristina Nery, President of the Human Rights Committee of the Oncology Hospital or with Dr. Hilda Rivera, Coordinator of Investigation at the phone 787-753-8433.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form with the stamp of the IRB approval for your records.

XV - CONSENT

I have read the information provided above or the information has been read to me. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed name of Witness (if applicable)

_____ _____
Signature of Witness (if applicable) Date

_____ _____
Cruz Maria Nazario, PhD
Signature of Principal Investigator Date

Samples can be stored for future use

☐ Yes (Participant's initials, _____) ☐ No, samples can only be used in the current study.

Universidad de Puerto Rico
Recinto de Ciencias Médicas
Escuela Graduada de Salud Pública
Apartado postal 365067, San Juan, Puerto Rico 00936-5067

CONSENTIMIENTO PARA DONAR MUESTRA DE TEJIDO O DE BLOQUE DEL TUMOR PARA INVESTIGACIÓN (PARTE 2)

TÍTULO: **Epidemiología de cáncer de mama en Puerto Rico**

NÚMERO DE PROTOCOLO:

PATROCINADOR:
Programa de investigación médica dirigido por el Congreso de los Estados Unidos para cáncer de mama, Departamento de Defensa CDMRP #BC060131USAMRMC-DOD

INVESTIGADORES: Cruz María Nazario-Delgado, Ph.D. (PI), Universidad de Puerto Rico
Jo Freudenheim, Ph.D. (Co-PI), University at Buffalo, Roswell Park Cancer Institute

Esta hoja de consentimiento puede tener palabras que usted no entienda. Por favor, pídale al investigador o a cualquier miembro del personal del estudio que le explique cualquier palabra o información que no entienda claramente. Usted puede llevarse a su casa una copia sin firmar de este consentimiento para pensar sobre este estudio o para discutirlo con su familia o amigos antes de tomar su decisión.

I. INTRODUCCIÓN:

Durante el proceso de confirmación y tratamiento del cáncer de seno, a usted le hicieron varios procedimientos que incluyeron biopsias (muestra pequeña del seno) y cirugía (extracción del cáncer). Usualmente, el hospital o el laboratorio guarda dentro de un bloque de parafina, el tumor que ha sobrado después de la cirugía.

II. PROPÓSITO:

Este estudio es parte de la investigación *Epidemiología de cáncer de mama en Puerto Rico* a la cual usted consintió en participar. Nos gustaría que nos permita sacar una muestra pequeña del bloque de tumor que ha sido guardado. La muestra de tejido podría ser usada en el futuro para estudiar las características y los cambios que ocurren dentro de ese tejido. La investigación con estas muestras de tejido puede ayudarnos a entender si esos cambios tienen relación con algunos alimentos, el cigarrillo, las hormonas y con otras exposiciones dañinas.

III. PROCEDIMIENTO:

Si usted autoriza, tomaremos una muestra de aproximadamente 25 pedacitos pequeños y finos del tumor (tan finos que se puede ver a través de ellos) para analizar en el laboratorio de Roswell Park Cancer Institute las características internas del tumor. Si su muestra llegara a ser usada junto con la de las otras personas para el desarrollo de un producto comercial, la Dra. Cruz M. Nazario y Dra. Jo Freudenheim serán dueñas de este producto y podrán patentizarlo. En ese caso, las doctoras Nazario y Freudenheim no la compensarán por el uso de la muestra de tejido. No recibirá notificación sobre el uso futuro de la muestra.

IV. PRIVACIDAD Y CONFIDENCIALIDAD:

La información sobre la privacidad y confidencialidad es igual a la que leyó en el consentimiento para el estudio. Usted puede rehusar a participar en esta parte del estudio.

V. PREGUNTAS:

Si tiene alguna pregunta sobre este estudio, puede contactar a la Dra. Cruz M. Nazario en el número de teléfono 787-758-2525 extensión 1-1429 o a Johan Hernández (Coordinadora del Proyecto) en el número 787-758-2525, extensión 1-1936.

Si tiene alguna pregunta sobre sus derechos como participante del estudio, puede contactar a la:
Oficina de Protección de Participantes Humanos en Investigación
Teléfono (787) 282-0018 o (787) 282-0010
Correo electrónico (E-mail): opphi.rcm@upr.edu

Si usted es paciente del Hospital Auxilio Mutuo, también se puede comunicar con el Dr. Armando Nazario, presidente del Comité de Revisión Institucional (IRB) al teléfono: (787) 250-7676.

O si usted es paciente del Hospital Oncológico Isaac González Martínez se puede comunicar con la Dra. Cristina Nery, Presidenta del Comité de Derechos Humanos del Hospital o con la Dra. Hilda Rivera, Coordinadora de Investigación al teléfono (787) 753-8433.

No firme este consentimiento a menos que haya tenido la oportunidad de hacer preguntas y recibir contestaciones satisfactorias para todas sus preguntas. Si firma y acepta participar en este estudio, recibirá una copia firmada, con el sello de aprobación de IRB y con la fecha de esta hoja de consentimiento para sus archivos.

VI. CONSENTIMIENTO

He leído la información en esta hoja de consentimiento o se me ha leído de manera adecuada. He tenido la oportunidad de hacer preguntas y todas mis preguntas sobre el estudio y mi participación han sido atendidas.

Yo autorizo el uso y la divulgación de mi información de salud a las entidades antes mencionadas en este consentimiento para los propósitos descritos anteriormente.

Al firmar esta hoja de consentimiento, no se ha renunciado a ninguno de los derechos legales.

Nombre del Participante (Nombre, Inicial, Apellidos)	Fecha nacimiento (día/mes/año)
Firma del Participante (o marca)	Fecha (día/mes/año)
Hospital que divulga el tejido	Fecha de hospitalización
Dra. Cruz María Nazario, Investigadora Principal	Fecha (día/mes/año)

Las muestras de tejido del bloque del tumor pueden ser utilizadas y guardadas para estudios futuros.

□ Sí (Iniciales del Participante _____) □ No, (Iniciales del Participante _____)

University of Puerto Rico
Medical Sciences Campus
Graduate School of Public Health
Box 365067, San Juan, Puerto Rico 00936-5067

CONSENT TO DONATE TISSUE OR TUMOR BLOCK SAMPLE FOR RESEARCH (PART 2)

TITLE: **Breast Cancer Epidemiology in Puerto Rico**

PROTOCOL NUMBER:

SPONSOR: **Congressionally Directed Medical Research Program's Breast Cancer Research Program, Department of Defense,**
CDMRP #BC060131 **USAMRMC-DOD.**

INVESTIGATORS: Cruz María Nazario-Delgado, Ph.D. (PI), University of Puerto Rico
Jo Freudenheim, Ph.D. (Co-PI), University at Buffalo, Roswell Park Cancer Institute

This consent form may contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about it or to discuss it with family or friends before making your decision.

I. INTRODUCTION

During the process to confirm or treat cancer you received various procedures including biopsies (small samples from breast) and surgery (remove cancer). Usually, the hospital or lab keeps the remaining tumor within a paraffin block.

II. PURPOSE

This study is part of the study *Breast Cancer Epidemiology in Puerto Rico* to which you have already consented to participate. We would like to obtain a small sample of the saved tumor block. The tissue sample could be used in the future to study the characteristics and changes that occur within that tissue. Research with tissue samples could help us understand if those changes are related to the food, cigarettes, hormones, or other harmful exposures.

III. PROCEDURE

If you authorize us, we will take a sample of approximately 25 very small and thin (so thin you can see thru them) samples of tissue and, in the Roswell Park Cancer Institute's lab, analyze the internal characteristics of the tumor. If your sample, along with the sample of other persons, is used to develop a commercial product, Dr. Cruz M. Nazario and Dr. Jo Freudenheim will own it and may patent the product. In such case, Drs. Nazario and Freudenheim will not compensate you for your tissue sample. You will not receive any notice of future uses of your samples.

IV. PRIVACY AND CONFIDENTIALITY

The information about the privacy and confidentiality is the same as the one you read in the previous consent for the study. You may refuse to participate in this part of the study.

V. QUESTIONS

If you have questions regarding this study or your participation in this study, or if at any time you feel you have experienced a research related injury, you may contact Dr. Cruz M. Nazario at this number: 787-758-2525 extension 1-1429 or Johan Hernández (Project Coordinator) at the 787-758-2525, extension 1-1936.

If you have any questions about your rights as a research subject you may contact:

Human Research Subjects Protection Office
University of Puerto Rico, Medical Sciences Campus
Telephone 787-282-0018 or 787-282-0010
E-mail: opphi.rcm@upr.edu

If you are patient of the Hospital Auxilio Mutuo, also, you can communicate with Dr. Armando Nazario, President of the Institutional Review Board (IRB) at the phone 787 250-7676.

Or if you are patient of the Isaac González Martinez Oncology Hospital, you can communicate with Dr. Cristina Nery, President of the Human Rights Committee of the Oncology Hospital or with Dr. Hilda Rivera, Coordinator of Investigation at the phone 787-753-8433.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. If you agree to be in this study, you will receive a signed and dated copy of this consent form with the stamp of the IRB approval for your records.

VI. CONSENT

I have read the information provided above or the information has been read to me. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Printed Name of Subject (First, middle, and last name)	Date of birth (day/month/year)
Signature of Subject (or mark)	Date (day/month/year)
Hospital or lab releasing the tumor block	Date (day/month/year)
Cruz María Nazario, Principal Investigator	Date

Tissue samples can be obtained and stored for future use.

☐ Yes (Participant's initials, _____) ☐ No (Participant's initials, _____)

University at Buffalo
The State University of New York

Health Sciences Institutional Review Board &
Institutional Animal Care and Use Committee

February 11, 2010

Jo Freudenheim, PhD
Social and Preventive Medicine
270 Farber Hall
South Campus

RE: Breast Cancer Epidemiology in Puerto Rico - DOD
HSIRB # SPM1010308E

Dear Dr. Freudenheim:

The Health Sciences Institutional Review Board (HSIRB) by expedited review has considered and approved your revised continuing submission for the protocol referenced above for a one-year period ending on **February 10, 2011**. The revisions do not substantially change the risks of the study. The HSIRB approval includes:

- Complete protocol/grant (dated 3/27/09)
- HSIRB date-stamped consent document – English (dated 4/6/09)
- HSIRB date-stamped consent document – Spanish (dated 4/6/09)
- HSIRB date-stamped consent to donate tissue or tumor block - English (dated 3/27/09)
- HSIRB date-stamped consent to donate tissue or tumor block - Spanish (dated 3/27/09)
- Revised study personnel- Added: Rosa Rosado – performing analyses
  Imar Mansilla - performing analyses
  Johan Hernandez Santiago –administrative

You are exempt from HIPAA requirements. The study does not involve the provision of health care and does not use any health information provided by a health care provider, health plan, or health care clearing house.

The attached consent document bears the HSIRB date-stamped approval period. Copies of this HSIRB date-stamped consent document must be used when enrolling subjects into your study.

HSIRB approval is given with the understanding that no changes may be made in the procedures to be followed nor the consent form(s) to be used until such modifications have been submitted to the HSIRB for review and have been given approval.

Any serious events/problems (SEP's) involving risk to human subjects must be reported promptly to the IRB.

Continuing HIPAA exempt revision

Prior to the expiration of this approval, you will receive notification of the need for updated information to be used for the project's periodic review. Information concerning implementation, and results to date, will be required at that time. Studies cannot be conducted beyond expiration date without re-approval by the IRB.

Sincerely yours,

Darlene Campanella, CIP
HSIRB Chair Designee

Enclosure: HSIRB date-stamped consent document – English (dated 4/6/09)
HSIRB date-stamped consent document – Spanish (dated 4/6/09)
HSIRB date-stamped consent to donate tissue or tumor block - English (dated 3/27/09)
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DC/cs

Continuing HIPAA exempt revision